Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
10 July 2015

Minutes – item no. 4

Centre 0088 (London Fertility Centre) – Interim Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Hannah Verdin Head of Regulatory Policy Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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 London Fertility Centre, centre 0088, has held a licence with the HFEA since May 1992. The centre provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 31 August 2017.

3. The panel noted that an inspection took place on 18 March 2015 and 13 April 2015.

4. The panel noted that the ownership of the centre changed in August 2014 and that a change of ownership does not impact on a centre's licence if premises, staff and practices remain unchanged. However, the panel noted that there have been significant staff changes at the centre since the change of ownership.

5. The panel noted that between August and December 2014 HFEA-held register data showed that 81 licensed treatment cycles (including eight cycles of donor insemination) were carried out at the centre. Between January and April 2015 there was a significant reduction in activity with only 13 cycles of treatment (including one cycle of donor insemination). Four of the cycles provided in 2015 were carried out post-inspection in April and a further 35 cycles were performed in May.

6. The panel noted that the HFEA does not yet hold one year's pregnancy outcome data for the time period since the change of ownership and so retrospective analysis of the centre's outcomes cannot be undertaken. It noted however that on-going trend analysis since August 2014 has shown a continued downward trend in the centre's clinical pregnancy rate in the last quarter. It further noted that more than half of the early outcome forms relating to these treatments have not been submitted to the HFEA register and this can impact on the accuracy of on-going trend analysis. The panel noted that the Inspectorate considered it disproportionate to make a recommendation at this time but the centre's success rates will be kept under review by the Inspectorate.

7. The HFEA does not yet hold one year's multiple births outcome data and so retrospective analysis of the centre's clinical multiple pregnancy rate for the time period since the change of ownership cannot be undertaken. It noted however that on-going trend analysis of the centre's clinical multiple pregnancy rate has shown a continued upward trend since August 2014: if this trend continues then the centre is unlikely to meet the 10% multiple live birth rate target. It further noted that a number of early outcome forms relating to treatments provided in this time period have not been submitted and this can impact on the accuracy of on-going trend analysis. The panel noted that the Inspectorate considered it disproportionate to make a recommendation at this time but the centre's clinical multiple pregnancy rates will be kept under review by the Inspectorate.

8. The panel noted that at the time of the interim inspection on 18 March 2015 and 13 April 2015, two critical and two major non-compliances were identified. In particular, the panel noted the non-compliances relating to the availability of staff and suitable practices. The panel noted that the PR did not provide a response to the Inspectorate's recommendations and that the absence of a response indicates a lack of engagement with the HFEA and the findings of this inspection.

9. The panel noted that in the course of the management review held on 25 June 2015, in accordance with the HFEA's Compliance and Enforcement Policy, further careful consideration was given to the risks as cited in this report relating to staffing and suitability of practices. On the basis of this further consideration, the Inspectorate recommends the continuation of the centre's licence based on the assumption and understanding that there are sufficient qualified and experienced staff available at centre 0088 and the centre is operating using practices that are employed at centres 0157 and 0206 (centres in the ARGC group), that have previously been assessed as suitable. The panel noted that due to a lack of engagement from the PR, the Inspectorate was only able to provide the panel with an assumption of these circumstances. Therefore, the Inspectorate also recommended that the PR should alert the HFEA if this assumption is materially not true.

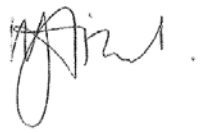
Decision

10. The panel was deeply concerned to learn of the lack of engagement from the PR, giving no response to the report or the recommendations made within it. The panel noted that the PR did not give any indication that he was committed to implementing the recommendations. The panel urged the PR to engage with the Inspectorate and fully implement all of the recommendations within the prescribed timescales and meet those deadlines set for 13 July 2015.

11. The panel endorsed the Inspectorate's recommendation to continue the centre's treatment and storage licence. The panel also endorsed the Inspectorate's recommendation that the PR should alert the HFEA if the Inspectorate's assumption about staff and suitable practices at the centre is materially not true.

12. It was the panel's view that the HFEA's Inspectorate has taken the initiative to take all steps necessary to ensure the continued activity of this centre with the best interests of the centre's patients at heart, and that the inspectorate should be commended for this. The panel noted that this was in stark contrast to the behaviour of and engagement from the centre's PR.

13. The panel agreed that the centre should be subject to ongoing monitoring.



Signed: Date: 21 July 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: London Fertility Centre
Centre number: 0088
Date licence issued: 01/09/2013
Licence expiry date: 31/08/2017
Additional conditions applied to this licence: None
Date of inspection: 18/03/2015 and 13/04/2015
Inspectors: Mrs Susan Jolliffe (Lead) Dr Douglas Gray, Mrs Shanaz Pasha.
Date of Executive Licensing Panel: 10 July 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 a scheduled 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 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 (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 Licence Holder (LH) named on the licence, Ms Madeleine Delaney, stood down in December 2014. The PR has not proposed an alternative LH and it is recommended that the licence is varied to remove reference to Ms Delaney as LH.

The Executive Licensing Panel is asked to note that there were recommendations for improvement in relation to two critical and two major area of non-compliance as follows:

'Critical areas of non- compliance:

- **The PR must ensure that sufficient qualified and competent staff are available.**
- **The PR must ensure that suitable practices are used in the provision of licensed treatments.**

'Major' areas of non- compliance:

- The PR must ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Directions 0005.
- The PR must ensure that an appropriately completed SAQ has been submitted.

The PR did not provided a response to these recommendations; the Executive has communicated via email (on two occasions) telephone (on two occasions) and special delivery postal courier (one occasion) in an attempt to elicit a response.

The absence of a response indicates a lack of engagement with the HFEA and the findings of this inspection.

As a consequence, management review meetings were held on 16 and 25 June 2015 in accordance with the HFEA's compliance and enforcement policy. The meeting on 16 June concluded that further informal efforts should be made to obtain a response and attempts were made to contact the PR by telephone but no contact was established.

In the course of the management review held on 25 June 2015, further careful consideration was given to the risks as cited in this report relating to staffing and suitability of practices. On the basis of this further consideration documented in Annex 1 of this report, the Executive recommends the continuation of the centre's licence. This recommendation is based on the assumption and understanding that there are sufficient qualified and experienced staff are available across the ARGC group and that centre 0088 is operating using practices that are employed at centres 0157 and 0206 that have previously been assessed as suitable. It is recommended that the PR should alert the HFEA if this assumption is materially not true.

Information about the centre

The London Fertility Centre is located in central London. The centre has been licensed by the HFEA since May 1992 and provides a full range of treatment services.

The ownership of the centre changed in August 2014. A change of ownership does not impact on a centre's licence if premises, staff and practices remain unchanged. It is also accepted that where a licensed centre becomes part of a larger group of licensed clinics then while some practices may be changed in line with those of the group these are practices that have hitherto been subject to HFEA scrutiny and considered suitable.

As a result of the change of ownership, the appointment of a new Person Responsible (PR), Mr Mohammed Taranissi, was approved by the Executive Licensing Panel on 06 November 2014.

Between August and December 2014 information submitted to the HFEA register indicates that 81 licensed treatment cycles (including eight cycles of donor insemination) were carried out at the centre. Between January and April 2015 there was a significant reduction in activity with only 13 cycles of treatment (including one cycle of donor insemination). Four of the cycles provided in 2015 were carried out post inspection in April. A further 35 cycles were performed in May.

The HFEA has been made aware that there have been significant staff changes at the centre since the change of ownership, including senior staff at the centre (the PR and LH for example) and the inspection team was advised by the PR that staff from the Assisted Reproduction and Gynaecology Centre (centre 0157) work at centre 0088 when required. When the inspection team attended the centre unannounced on 18 March 2015, no HFEA licensed activity was being carried out and no laboratory staff were present on site. The inspection team was provided with a brief tour of the premises but were not able to review treatment records or review the records of consent relating to gametes and /or embryos stored at the centre, therefore a further inspection was undertaken on 13 April 2015 to assess whether gametes and embryos were being stored at the centre in accordance with the gamete provider's consent.

The inspection team was advised by the PR that the records of treatments provided before the change of ownership have not all been retained by the new owners although there were electronic records of consent to storage seen at inspection. This means that the current PR cannot assume responsibility for any corrections or updates to HFEA register information relating to treatments that took place before the change of ownership. The new PR is also not responsible for payment of fees relating to the centre's activities before August 2014 and it is not considered proportionate to hold the current PR to account for performance (in terms of success rates) and alerts relating to the centre's clinical multiple pregnancy rate that predate the change of ownership in August 2014.

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]

The HFEA does not yet hold one year's outcome data for the time period since the change of ownership and so retrospective analysis of the centre's outcomes cannot be undertaken. It is noted however that on-going trend analysis since August 2014 has shown a continued downward trend in the centre's clinical pregnancy rate in the last quarter. It is noted that more than half of the early outcome forms relating to these treatments have not been submitted to the HFEA register and this can impact on the accuracy of on-going trend analysis[2]. It is considered disproportionate to make a recommendation at this time but the centre's success rates will be kept under review by the executive.

Multiple births[3]

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

The HFEA does not yet hold one year's outcome data[4] and so retrospective analysis of the centre's clinical multiple pregnancy rate for the time period since the change of ownership cannot be undertaken. It is noted however that on-going trend analysis of the centre's clinical multiple pregnancy rate has shown a continued upward trend since August 2014: if this trend continues then the centre is unlikely to meet the 10% multiple live birth rate target. It is noted that a number of early outcome forms relating to treatments provided in this time period have not been submitted and this can impact on the accuracy of on-going trend analysis. It is considered disproportionate to make a recommendation at this time but the centre's clinical multiple pregnancy rates will be kept under review by the executive.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur.

There was no activity at the centre on either of the occasions when the inspection team were on site so no witnessing practices could be observed during the inspection and staff were not available to describe witnessing practices.

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 recorded in their records

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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's ongoing trend analysis assumes that treatment has not resulted in a clinical pregnancy if an early outcome form is not submitted within 3 months of the treatment date as required.

[3] 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%.

4 Outcome data is analysed by year as analysis of data for a shorter period is not considered statistically robust.

and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting of such consent decisions through the EDI system is accurate, so that patient information is not disclosed without consent.

Centre staff reported that records were not available for review at the inspection and so it was not possible to conduct an audit of the consent decisions reported to the HFEA against those recorded in patient records. The HFEA is continuing to liaise with the PR to understand how records of consent can be audited.

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that gametes and embryos currently in store are being stored within their terms of the consent of the gamete providers. The storage periods for one set of embryo as recorded on the centre's database were cross checked against the consent given by the gamete providers and they were being stored in accordance with the consent provided.

Staffing

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

There was no licensed activity taking place on the day of inspection. The PR advised the inspection team that a member of the laboratory team from centre 0157 performs daily checks on the facilities at the centre (including the theatres, laboratory and storage facilities).

It is not clear how staff already employed to provide licensed treatment at two existing HFEA licensed clinics can be made available to staff a third licensed centre. The HFEA therefore does not have information to support a conclusion that suitably trained staff are available in sufficient number (see recommendation 1).

Patient experience

During the inspection visit there were no patients to speak with.

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

Correspondence requesting that the PR provide an updated self-assessment questionnaire (SAQ) relating to this centre's practices and procedures was sent to the PR on 3 November 2014 and reminders were sent on 23 February 2015 and 05 March 2015. The PR did not provide am updated SAQ prior to the inspection. The inspection proceeded on the assumption that there has been no change to the self-assessment although it is acknowledged that this assessment was completed by the previous PR (see recommendation 4)

It is considered likely that the change of ownership may have resulted in changes in the centre's practices. It is acknowledged that the PR is responsible for two other HFEA

licensed clinics and that the practices of these licensed clinics (centres 0157 and 0206) have previously been assessed as suitable. The executive assumes that the practices of these licensed centres are now employed at centre 0088 because the PR advised that staff from centres 0157 and 0206 are now working in centre 0088 (recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following a renewal inspection in 2013 recommendations for improvement were made in relation to two critical and three major areas of non-compliance, and 8 'other' areas of practice that require improvement.

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

On-going monitoring of centre success rates and risk tool alerts

No risk tool alerts in connection with performance, register submissions or payment of fees relevant to the time period after the change of ownership have been issued to the PR.

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's on-going monitoring suggests that the centre is not submitting early outcome data to the HFEA as required (see recommendation 3).

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 carried out.

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 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
1. There was no information available at the time of the inspection to support a conclusion that the PR has ensured that personnel will be available in sufficient number and are qualified and competent for the tasks they perform (standard licence condition, SLC, T12).	In responding to this report the PR should explain staffing arrangements. The PR should provide assurance of the staffing, by indicating the number of staff that are present in the centre when it is operational; their qualifications, and; the number of cycles that can be safely accommodated		The PR did not provide any response to the interim inspection report. To ensure that the report was received, the report was sent by e-mail, post and courier. Efforts were made to elicit a response, but phone calls to the PR have not been answered or, when the centre staff answered, the PR was not available to speak to the lead inspector. Therefore the lead inspector initiated a management review meeting on 16 June in line with the Compliance and Enforcement policy; Section 4. 4.2 (a) (e), at which it was agreed that further informal action would be taken to contact the PR and to review activity and staffing levels at the centre. A further management review meeting was held on 25 June to

	with the proposed staffing levels. The PR should also update the centre's staff list through the HFEA's clinic portal to ensure compliance with SLC T44 by the time this report is considered by a licensing committee.		consider the review of activity levels. The review of activity levels noted that information provided by or on behalf of the PR through the HFEA's clinic portal since the change of ownership, indicates that new staff have been appointed to work at centre 0088 since the change of ownership. This includes 11 non-HCPC registered scientists and six HCPC registered scientists. Having reviewed the staff list at centres 0088 0157 and 0206 it appears that the three HCPC registered scientists are also reported as working at one other centre in the group. Although there was very little licensed activity being undertaken at the time of the inspection, the PR reported verbally that activity could be resumed at any time. As stated in the body of the report, the executive were concerned about how staff already employed to provide licensed treatment at two existing HFEA licensed clinics could be made available to staff a third licensed centre. It is noted that since the inspection, activity has been resumed at centre 0088 with 35 cycles reported as provided in May. To assess the risks associated with this the executive undertook an analysis of activity across the whole ARGC group. That analysis has shown that although the number of treatment cycles increased at centre 0088 from three and four cycles respectively in March and April to 35 in May 2015, there was a concomitant reduction in the number performed at centre 0206 (from 69 in March and April to 39 in May) and this meant that the average activity across the whole group remained largely constant. On the basis that overall group activity is broadly unchanged

			the HFEA executive consider that sufficient staff are employed by the group to provide treatment at the current group activity levels.
2. The change of ownership at the centre may have resulted in a change in practice. This means that at the time of the inspection, no information was available to support a conclusion that the centre's practices remain suitable (SLC T2).	In responding to this report the PR should confirm whether the suitable practices used at centres 0157 and 0206 are to be employed in the provision of licensed treatment at centre 0088.		Following the change of ownership in August 2014 information as cited above suggests that new staff are working at the centre but that some of the new staff members also work at other centres in the group. The HFEA has previously been reassured that practices used at centres 0157 and 0206 are the same and this has been acknowledged in inspection reports. Centre 0088 is now part of that same group with the same PR. The management review meeting on 25 June concluded that after careful further consideration of the risks, based on the observation that some staff employed at centre 0088 are also employed at other centres across the group it is reasonable to assume that these staff are working to the same practices which have previously been considered suitable. This is assumed to be the case in the absence of the PR advising otherwise.

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
3. The PR has not provided early outcome information required by the HFEA within the required timescales. (SLC T9e, T41 and General Directions 0005	The PR must ensure that the outcome of treatment is reported to the HFEA within the timeframe required by General Directions 0005. Treatment outcomes have not been reported within that timeframe should be reported by 13 July 2015. The EDI contact for centre 0088 should be made known to the centre inspector by 13 July 2015. The PR should review the process for submitting data to the HFEA. The inspector should be informed of the outcome of the review; any corrective actions identified as		The executive are continuing to work with the PR to resolve these issues.

	necessary and the timescale for their implementation by 13 July 2015.		
4. The PR did not submit a reviewed SAQ in support of this inspection despite several reminders to do so. (SLC T4 and General Directions 0008). It is noted that non submission of an updated SAQ is cited in the 2015 renewal inspection report relevant to centre 0206 as a critical non-compliance: the non-compliance was escalated from major because the PR had failed to provide an updated SAQ prior to the previous inspection at 0206.	An appropriately completed SAQ should be submitted via the Clinic Portal by 13 July 2015.		No SAQ has been submitted.

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement

Additional information from the Person Responsible